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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,842	10/26/2001	Michel J.N. Cormier	33392-754.201	2394

66956 7590 04/13/2007  
WILSON SONSINI GOODRICH & ROSATI & MACROFLUX CORP.  
650 PAGE MILL ROAD  
PALO ALTO, CA 94304

EXAMINER
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CAMERON, ERMA C

ART UNIT	PAPER NUMBER
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1762

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/045,842	<b>Applicant(s)</b> CORMIER ET AL.	
	<b>Examiner</b> Erma Cameron	<b>Art Unit</b> 1762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 February 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18-24, 28-35 and 47 is/are pending in the application.
- 4a) Of the above claim(s) 28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18-24, 29-35, 47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Response to Amendment***

#### ***Election/Restrictions***

1. On 8/8/2005, the applicant elected dipping as the species to be examined, as opposed to spraying. Accordingly, claim 28 (which is drawn to applying the agent in a pattern) is withdrawn from consideration as being directed to a non-elected species. Dipping would not produce a pattern of agent; spraying is capable of producing a pattern. See 37 CFR 1.142(b) and MPEP § 821.03.

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 22, 34 and 35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not

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described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

a) Claim 22: the examiner cannot find where in the specification as originally filed it is stated that the thickness of the microprotrusion is less than 25 micrometers.

b) Claims 34 and 35: the examiner cannot find where in the specification as originally filed it is stated that the loading is less than 1 mg/cm<sup>2</sup> or less than 0.5 mg/cm<sup>2</sup>.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a) Claim 23: it appears that “and” should precede “growth regulatory factor”.

***Claim Rejections - 35 USC § 102***

6. The rejection of Claims 18-22, 28-33, and 47 under 35 U.S.C. 102(e) as being anticipated by Dalton (WO 02/07813) is withdrawn because of the amendment filed 10/4/2006.

***Claim Rejections - 35 USC § 103***

7. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

8. The rejection of Claims 23-24 and 34-35 under 35 U.S.C. 103(a) as being unpatentable over Dalton (WO 02 / 07813) is withdrawn because of the amendment filed 10/4/2006.

9. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Szumski et al (3470011).

'011 teaches making a coating of a biological agent such as a vaccine on fine tines that will be used as an intracutaneous injector. The coating is formed by dipping the tines in an aqueous solution of the agent (see Abstract; 1:28-62, 2:38-48; see Examples).

'011 does not teach the details of the size of the tines or the amount of coating, but it would have been obvious to one of ordinary skill in the art to have optimized these parameters because they are known to be relevant to transdermal injection.

'011 does not teach the solubility or viscosity of the agent solution, but because '011 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

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10. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palmer (6537242).

'242 teaches microneedles (10 to 200 microns long) to penetrate the stratum corneum to deliver a dried drug coating of antibiotic, vaccine, protein, etc. (2:39-49; 4:13-5:27; 6:65-7:5; 10:3-1). The needle size overlaps with that claimed by applicant.

'242 does not teach the solubility or viscosity of the agent solution, but because '242 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

11. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Powell (6589202).

'202 teaches transdermal microneedles (50 to 2000 microns long) with a drug, vaccine, antibiotic, protein, etc. coating (see Abstract; 2:31-41; 4:21-44; 6:36-50; 8:7-46). The needle size overlaps with that claimed by applicant.

'202 does not teach the solubility or viscosity of the agent solution, but because '202 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

12. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/10630.

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'630 teaches using microprobes about 10-300 microns long to deliver drugs such as antibiotics, hormone, proteins, etc. into animal epidermal cells. The drugs are applied to the microprobes from an aqueous solution (4:3-15, 9:15-37; 11:24-12:14; 13:4-14; 14:1-8).

'630 does not teach the details of the size of the tines or the amount of coating, but it would have been obvious to one of ordinary skill in the art to have optimized these parameters because they are known to be relevant to transdermal injection.

'630 does not teach the solubility or viscosity of the agent solution, but because '630 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

13. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ginaven et al (5457041).

'041 teaches coating microneedles with a coating of proteins or hormones to deliver these agents into animal or plant target cells. This would be inclusive of dermal cells. The coating is formed from an aqueous solution. The needles are 25 microns long and 3 microns wide. The needle size overlaps with that claimed by applicant. (See Abstract; 1:9-18; 3:29-5:15; 7:3-8:39).

'041 does not teach the solubility or viscosity of the agent solution, but because '041 is using agents that are similar to those used by applicant, these parameters are expected to be similar.

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14. Claims 18-24, 29-35 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cormier et al (US2002 / 010292).

‘292 teaches coating stratum corneum-piercing microprotrusion arrays with various agents such as peptides, desmopressin, vaccines etc for transdermal delivery. The microprotrusions are less than 500 micrometers [0009], [0059-[0065].

‘292 does not teach the solubility or viscosity of the agent solution used in the coating, but because ‘292 teaches using agents that are the same as claimed by applicant, these parameters will be the same or similar.

### ***Double Patenting***

15. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

16. Claims 18-24, 29-35, and 47 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 54-64 of copending Application No. 11/034,891.

As outlined in the previous office action, although the conflicting claims are not identical, they are not patentably distinct from each other because the Application teaches the limitations of the claims and only fails to teach the dose, solubility, and viscosity of the agent of the instant claims. However, claims in the 11/034,891 application are directed to the same active agents as



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the claims and specification of the instant application, which would inherently be useful in the same dosage, solubility, and viscosity as instantly claimed,

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant correctly cites the MPEP and asks “does any claim in the application define an invention that is merely an obvious variation of an invention claimed in the patent?”, but then Applicant argues that the instant application does not describe or suggest the limitations of the patent.

It is not required for the instant claims to describe or suggest the limitations of the co-pending case. Conversely, as outlined in the MPEP and in Examiner’s re-stated rejection above, the co-pending case need only describe or suggest the limitations of the instant claims. One of ordinary skill in the art regarding the co-pending case would have deemed the instant claims to be “an obvious variation” thereof as required by the MPEP. Removal of language directed to counter-ions, etc. is merely a broadening of the claim. And the additional limitations of the instant claims directed to dose, solubility, and viscosity are inherently useful for the given active agents, as outlined above.

17. Claims 18-24, 29-35 and 47 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 28-54 of copending Application No. 10/127108, over claims 21-39 of copending Application No. 10/674626, over

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claims 10-13 of copending Application No. 10/972231, claims 33-38 of copending Application No. 11/201625, claims 32-34 of copending Application no. 11/206698 and claims 30-35 of copending Application No. 11/355856. Although the conflicting claims are not identical, they are not patentably distinct from each other because the coatings on the microprotrusions of the Applications are merely variations of and included in the “pharmacologically active agent” of the instant application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Erma Cameron whose telephone number is 571-272-1416. The examiner can normally be reached on Monday through Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ERMA CAMERON  
PRIMARY EXAMINER

April 11, 2007

*Erma Cameron*  
ERMA CAMERON  
PRIMARY EXAMINER

Erma Cameron  
Primary Examiner  
Art Unit 1762